

PCT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 12 September 2000 (12.09.00)	
International application No. PCT/GB00/00123	Applicant's or agent's file reference MGH/JM/P10338PC
International filing date (day/month/year) 19 January 2000 (19.01.00)	Priority date (day/month/year) 19 January 1999 (19.01.99)
Applicant FOSTER, Peter, Reynolds et al	

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

03 August 2000 (03.08.00)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Pascal Piriou Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

PCT



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 24 APR 2001

W/ISO

14

Applicant's or agent's file reference MGH/HS/P10338PC		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB00/00123	International filing date (day/month/year) 19/01/2000	Priority date (day/month/year) 19/01/1999	
International Patent Classification (IPC) or national classification and IPC A61L2/02			
Applicant COMMON SERVICES AGENCY et al.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none">I <input checked="" type="checkbox"/> Basis of the reportII <input type="checkbox"/> PriorityIII <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicabilityIV <input type="checkbox"/> Lack of unity of inventionV <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statementVI <input checked="" type="checkbox"/> Certain documents citedVII <input type="checkbox"/> Certain defects in the international applicationVIII <input checked="" type="checkbox"/> Certain observations on the international application			
Date of submission of the demand 03/08/2000		Date of completion of this report 20.04.2001	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer Maremonti, M Telephone No. +49 89 2399 8440 	

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/00123

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-15 as originally filed

Claims, No.:

1-14 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/00123

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	4-6,10,13
	No:	Claims	1-3,7-9,11,12,14
Inventive step (IS)	Yes:	Claims	NONE
	No:	Claims	1-14
Industrial applicability (IA)	Yes:	Claims	1-14
	No:	Claims	NONE

2. Citations and explanations
see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: EP-A-0 798 003 cited in the application

D2: Hou K. et al: 'Capture of latex beads, bacteria, endotoxin, and viruses by charge-modified filters', APPLIED AND ENVIRONMENTAL MICROBIOLOGY, US, WASHINGTON,DC, vol. 40, no. 5, 1 November 1980 (1980-11-01), pages 892-896, XP002057339 ISSN: 0099-2240.

D3: WO 96 05846 A

D4: GB-A-2 045 828

- 1.1 The present application does not meet the requirements of the PCT, because the subject-matter of independent claim 1 is not novel in the sense of Article 33(2) PCT. Indeed, document D1 discloses a method of removal of viruses from an aqueous liquid containing proteins, which method comprises the step of passing said liquid through a depth filter formed of a matrix comprising a porous element having a pore size ranging from 0.25 to 2 μm (cf. claims 1, 2 and 5). Additionally, the method disclosed in D1 is regarded as to be suitable for the removal of infective prion proteins associated with transmissible spongiform encephalopathies. Therefore, all features mentioned in claim 1 are disclosed in D1.

It should be noted that all features mentioned in claim 1 are also known from document D2 (cf. abstract, paragraph 'Material and Methods' on p. 892), which, hence, anticipates claim 1, as well.

- 1.2 Independent claim 14 is formulated as a product-by-process claim. Indeed, it concerns any liquid which has been subjected to prion removal according to the method of anyone of claims 1-13. No indication is given about the intrinsic features of the claimed product. Such a product-by-process formulation is only admissible if the product as such is novel and inventive over the available, known products and if it cannot be defined in any other way, i.e. by means of its intrinsic features. This is clearly not the case here with the present application, where the

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/00123

claimed product is, in fact, **any liquid** from which prions have been removed, i.e. also simply water. Additionally, prion removal is disclosed, for example, in document D3, which describes, in particular, a process for the removal of infected prions associated with transmissible spongiform encephalopathies (cf. claims 1 and 2). Hence, no difference can be seen between the liquid claimed in claim 14 and the product obtained by the process of D3. Therefore, the subject-matter of independent claim 14 is not novel in the sense of Article 33(2) PCT.

2. Dependent claims 2-13 do not appear to contain any additional feature which, in combination with the features of any claim to which they refer, meets the requirements of the PCT with respect to novelty and inventive step (Articles 33(2) and (3) PCT). Indeed, the features mentioned in claims 2, 3, 7-9, 11 and 12 are known from D1 and D2 (cf. D1: claims 1, 2 and 5, p. 3, l. 26-27 and l. 59; D2: paragraph 'Filters' on p. 892 and Table 4 on p. 894). The features mentioned in the remaining claims are regarded as obvious design possibilities for a person skilled in the art of liquid filtration (cf. for example D4: claims 8 and 9).
3. The subject-matter of all claims is regarded as to be industrially applicable (Articles 33(4) PCT).

Re Item VI

Certain cited documents

Certain published documents (Rule 70.10)

The priority of the present application was not checked. If the priority were not valid then the document: Foster P.R.: 'Assessment of the potential of plasma fractionation processes to remove causative agents of transmissible spongiform encephalopathy.' TRANSFUSION MEDICINE, (1999-MAR) 9 (1) 3-14. REF: 60 , XP000904838, would become relevant as far as novelty and inventive step are concerned.

Re Item VIII

Certain observations on the international application

1. According to the description, examples 2 and 3 on p. 11 and 12 represent

comparative tests, i.e. they are not expressing the method of the invention. Nevertheless, the methods adopted in these examples comprise the step of passing a liquid containing infective prions through a depth filter, the composition and porosity of which are clearly the same as in the method claimed in claim 1 (see Table 1 on p. 14). In other words, the methods reported in examples 2 and 3 fall within the scope of independent claim 1. Since, according to the description (see p. 12, l. 2-4 and 18-20) the methods of examples 2 and 3 are not able to solve the problem of the invention (they do not remove prions), then the protection of claim 1 is extended also to embodiments that are not able to perform the invention. It seems, therefore, that some **essential** features are missing in claim 1 (Article 6 PCT).

2. In independent claim 1, the term "natural product" is so vague and general to actually include every existing substance. According to the description (see in particular examples 1 and 4), the claimed method is indeed specifically applied to aqueous liquids containing active proteins and blood plasma products. Therefore, claim 1 should have been restricted to the treatment of the above-mentioned liquids by including the features revealed in claims 11 and 12 (Article 6 PCT).
3. According to the description (see p. 6, l. 18-21), the use of a charged material within the filter may contribute to the reduction of the activity of the protein contained in the liquid to be treated. This appears to be in contradiction with the teaching of D1, where it is clearly stated that the use of a charged depth filter does not adversely affect the protein activity (cf. claim 1).

PATENT COOPERATION TREATY

MGH

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)

To:

McCALLUM, William P
CRUIKSHANK & FAIRWEATHER
19 Royal Exchange Square
Glasgow G1 3AE
GRANDE BRETAGNE

Date of mailing
(day/month/year) 20.04.2001

Applicant's or agent's file reference
MGH/HS/P10338PC

IMPORTANT NOTIFICATION

International application No.
PCT/GB00/00123

International filing date (day/month/year)
19/01/2000

Priority date (day/month/year)
19/01/1999

Applicant
COMMON SERVICES AGENCY et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/



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D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized officer

Ipizarar, P

Tel. +49 89 2399-8131



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference MGH/HS/P10338PC	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB00/00123	International filing date (day/month/year) 19/01/2000	Priority date (day/month/year) 19/01/1999
International Patent Classification (IPC) or national classification and IPC A61L2/02		
Applicant COMMON SERVICES AGENCY et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


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☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 03/08/2000	Date of completion of this report 20.04.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Maremonti, M Telephone No. +49 89 2399 8440



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/00123

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-15 as originally filed

Claims, No.:

1-14 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

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- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
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- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
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- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/00123

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	4-6,10,13
	No:	Claims	1-3,7-9,11,12,14
Inventive step (IS)	Yes:	Claims	NONE
	No:	Claims	1-14
Industrial applicability (IA)	Yes:	Claims	1-14
	No:	Claims	NONE

2. Citations and explanations
see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

s e separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

s e separate sheet

R I t m V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: EP-A-0 798 003 cited in the application

D2: Hou K. et al: 'Capture of latex beads, bacteria, endotoxin, and viruses by charge-modified filters', APPLIED AND ENVIRONMENTAL MICROBIOLOGY, US, WASHINGTON,DC, vol. 40, no. 5, 1 November 1980 (1980-11-01), pages 892-896, XP002057339 ISSN: 0099-2240.

D3: WO 96 05846 A

D4: GB-A-2 045 828

1.1 The present application does not meet the requirements of the PCT, because the subject-matter of independent claim 1 is not novel in the sense of Article 33(2) PCT. Indeed, document D1 discloses a method of removal of viruses from an aqueous liquid containing proteins, which method comprises the step of passing said liquid through a depth filter formed of a matrix comprising a porous element having a pore size ranging from 0.25 to 2 μm (cf. claims 1, 2 and 5). Additionally, the method disclosed in D1 is regarded as to be suitable for the removal of infective prion proteins associated with transmissible spongiform encephalopathies. Therefore, all features mentioned in claim 1 are disclosed in D1.

It should be noted that all features mentioned in claim 1 are also known from document D2 (cf. abstract, paragraph 'Material and Methods' on p. 892), which, hence, anticipates claim 1, as well.

1.2 Independent claim 14 is formulated as a product-by-process claim. Indeed, it concerns any liquid which has been subjected to prion removal according to the method of anyone of claims 1-13. No indication is given about the intrinsic features of the claimed product. Such a product-by-process formulation is only admissible if the product as such is novel and inventive over the available, known products and if it cannot be defined in any other way, i.e. by means of its intrinsic features. This is clearly not the case here with the present application, where the

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/00123

- claimed product is, in fact, **any liquid** from which prions have been removed, i.e. also simply water. Additionally, prion removal is disclosed, for example, in document D3, which describes, in particular, a process for the removal of infected prions associated with transmissible spongiform encephalopathies (cf. claims 1 and 2). Hence, no difference can be seen between the liquid claimed in claim 14 and the product obtained by the process of D3. Therefore, the subject-matter of independent claim 14 is not novel in the sense of Article 33(2) PCT.
2. Dependent claims 2-13 do not appear to contain any additional feature which, in combination with the features of any claim to which they refer, meets the requirements of the PCT with respect to novelty and inventive step (Articles 33(2) and (3) PCT). Indeed, the features mentioned in claims 2, 3, 7-9, 11 and 12 are known from D1 and D2 (cf. D1: claims 1, 2 and 5, p. 3, l. 26-27 and l. 59; D2: paragraph 'Filters' on p. 892 and Table 4 on p. 894). The features mentioned in the remaining claims are regarded as obvious design possibilities for a person skilled in the art of liquid filtration (cf. for example D4: claims 8 and 9).
 3. The subject-matter of all claims is regarded as to be industrially applicable (Articles 33(4) PCT).

Re Item VI

Certain cited documents

Certain published documents (Rule 70.10)

The priority of the present application was not checked. If the priority were not valid then the document: Foster P.R.: 'Assessment of the potential of plasma fractionation processes to remove causative agents of transmissible spongiform encephalopathy.' TRANSFUSION MEDICINE, (1999 MAR) 9 (1) 3-14. REF: 60 , XP000904838, would become relevant as far as novelty and inventive step are concerned.

Re Item VIII

Certain observations on the international application

1. According to the description, examples 2 and 3 on p. 11 and 12 represent

comparative tests, i.e. they are not expressing the method of the invention. Nevertheless, the methods adopted in these examples comprise the step of passing a liquid containing infective prions through a depth filter, the composition and porosity of which are clearly the same as in the method claimed in claim 1 (see Table 1 on p. 14). In other words, the methods reported in examples 2 and 3 fall within the scope of independent claim 1. Since, according to the description (see p. 12, l. 2-4 and 18-20) the methods of examples 2 and 3 are not able to solve the problem of the invention (they do not remove prions), then the protection of claim 1 is extended also to embodiments that are not able to perform the invention. It seems, therefore, that some **essential** features are missing in claim 1 (Article 6 PCT).

2. In independent claim 1, the term "natural product" is so vague and general to actually include every existing substance. According to the description (see in particular examples 1 and 4), the claimed method is indeed specifically applied to aqueous liquids containing active proteins and blood plasma products. Therefore, claim 1 should have been restricted to the treatment of the above-mentioned liquids by including the features revealed in claims 11 and 12 (Article 6 PCT).
3. According to the description (see p. 6, l. 18-21), the use of a charged material within the filter may contribute to the reduction of the activity of the protein contained in the liquid to be treated. This appears to be in contradiction with the teaching of D1, where it is clearly stated that the use of a charged depth filter does not adversely affect the protein activity (cf. claim 1).

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference
(if desired) (12 characters maximum) MGH/JM/P10338PC

Box No. I TITLE OF INVENTION

TREATING PROTEIN-CONTAINING LIQUIDS

Box No. II APPLICANT

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

COMMON SERVICES AGENCY
Trinity Park House
South Trinity Road
EDINBURGH EH5 3SE
UNITED KINGDOM

☐ This person is also inventor.

Telephone No.

Facsimile No.

Teleprinter No.

State (that is, country) of nationality:

GB

State (that is, country) of residence:

GB

This person is applicant for the purposes of:

☐ all designated States

☒ all designated States except the United States of America

☐ the United States of America only

☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

FOSTER PETER REYNOLDS
Flat 3F1
5, St. Stephen Street
EDINBURGH EH3 5AN
UNITED KINGDOM

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

GB

State (that is, country) of residence:

GB

This person is applicant for the purposes of:

☐ all designated States

☐ all designated States except the United States of America

☒ the United States of America only

☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE: OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:

☐ agent

☐ common representative

Name and address:

McCALLUM, William Potter; MacDOUGALL, Donald Carmichael; SZCZUKA, Jan Tymoteusz; NAISMITH, Robert Stewart; HORNER, Martin Grenville, SHANKS, Andrew; NEWELL, Campbell; KERR, Sheila Agnes Fife; MORELAND, David; GODWIN, Edgar James; all of

CRUIKSHANK & FAIRWEATHER, 19 ROYAL EXCHANGE SQUARE,
GLASGOW G1 3AE, UNITED KINGDOM (GB)

Telephone No.
0141 221 5767

Facsimile No.
0141 221 7739

Teleprinter No.

☐ Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

WELCH ANNE GILLIAN
31 The Firs
Dalgety Bay
FIFE KY11 9UH
UNITED KINGDOM

This person is:

- ☐ applicant only
☒ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

GB

State (that is, country) of residence:

GB

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

- ☐ applicant only
☐ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

- ☐ applicant only
☐ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

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This person is:

- ☐ applicant only
☐ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No. V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes; at least one must be marked):

Regional Patent

- ☒ AP ARIPO Patent: GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SL Sierra Leone, SZ Swaziland, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ EA Eurasian Patent: AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ EP European Patent: AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ OA OAPI Patent: BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line)

National Patent (if other kind of protection or treatment desired, specify on dotted line):

- | | |
|--|--|
| <input checked="" type="checkbox"/> AE United Arab Emirates | <input checked="" type="checkbox"/> LR Liberia |
| <input checked="" type="checkbox"/> AL Albania | <input checked="" type="checkbox"/> LS Lesotho |
| <input checked="" type="checkbox"/> AM Armenia | <input checked="" type="checkbox"/> LT Lithuania |
| <input checked="" type="checkbox"/> AT Austria | <input checked="" type="checkbox"/> LU Luxembourg |
| <input checked="" type="checkbox"/> AU Australia | <input checked="" type="checkbox"/> LV Latvia |
| <input checked="" type="checkbox"/> AZ Azerbaijan | <input checked="" type="checkbox"/> MD Republic of Moldova |
| <input checked="" type="checkbox"/> BA Bosnia and Herzegovina | <input checked="" type="checkbox"/> MG Madagascar |
| <input checked="" type="checkbox"/> BB Barbados | <input checked="" type="checkbox"/> MK The former Yugoslav Republic of Macedonia |
| <input checked="" type="checkbox"/> BG Bulgaria | <input checked="" type="checkbox"/> MA MOROCCO |
| <input checked="" type="checkbox"/> BR Brazil | <input checked="" type="checkbox"/> MN Mongolia |
| <input checked="" type="checkbox"/> BY Belarus | <input checked="" type="checkbox"/> MW Malawi |
| <input checked="" type="checkbox"/> CA Canada | <input checked="" type="checkbox"/> MX Mexico |
| <input checked="" type="checkbox"/> CH and LI Switzerland and Liechtenstein | <input checked="" type="checkbox"/> NO Norway |
| <input checked="" type="checkbox"/> CN China | <input checked="" type="checkbox"/> NZ New Zealand |
| <input checked="" type="checkbox"/> CU Cuba | <input checked="" type="checkbox"/> PL Poland |
| <input checked="" type="checkbox"/> CZ Czech Republic | <input checked="" type="checkbox"/> PT Portugal |
| <input checked="" type="checkbox"/> DE Germany | <input checked="" type="checkbox"/> RO Romania |
| <input checked="" type="checkbox"/> DK Denmark | <input checked="" type="checkbox"/> RU Russian Federation |
| <input checked="" type="checkbox"/> EE Estonia | <input checked="" type="checkbox"/> SD Sudan |
| <input checked="" type="checkbox"/> ES Spain | <input checked="" type="checkbox"/> SE Sweden |
| <input checked="" type="checkbox"/> FI Finland | <input checked="" type="checkbox"/> SG Singapore |
| <input checked="" type="checkbox"/> GB United Kingdom | <input checked="" type="checkbox"/> SI Slovenia |
| <input checked="" type="checkbox"/> GD Grenada | <input checked="" type="checkbox"/> SK Slovakia |
| <input checked="" type="checkbox"/> GE Georgia | <input checked="" type="checkbox"/> SL Sierra Leone |
| <input checked="" type="checkbox"/> GH Ghana | <input checked="" type="checkbox"/> TJ Tajikistan |
| <input checked="" type="checkbox"/> GM Gambia | <input checked="" type="checkbox"/> TM Turkmenistan |
| <input checked="" type="checkbox"/> HR Croatia | <input checked="" type="checkbox"/> TR Turkey |
| <input checked="" type="checkbox"/> HU Hungary | <input checked="" type="checkbox"/> TT Trinidad and Tobago |
| <input checked="" type="checkbox"/> ID Indonesia | <input checked="" type="checkbox"/> UA Ukraine |
| <input checked="" type="checkbox"/> IL Israel | <input checked="" type="checkbox"/> UG Uganda |
| <input checked="" type="checkbox"/> IN India | <input checked="" type="checkbox"/> US United States of America |
| <input checked="" type="checkbox"/> IS Iceland | <input checked="" type="checkbox"/> TZ Tanzania |
| <input checked="" type="checkbox"/> JP Japan | <input checked="" type="checkbox"/> UZ Uzbekistan |
| <input checked="" type="checkbox"/> KE Kenya | <input checked="" type="checkbox"/> VN Viet Nam |
| <input checked="" type="checkbox"/> KG Kyrgyzstan | <input checked="" type="checkbox"/> YU Yugoslavia |
| <input checked="" type="checkbox"/> KP Democratic People's Republic of Korea | <input checked="" type="checkbox"/> ZA South Africa |
| <input checked="" type="checkbox"/> KR Republic of Korea | <input checked="" type="checkbox"/> ZW Zimbabwe |
| <input checked="" type="checkbox"/> KZ Kazakhstan | Check-boxes reserved for designating States which have become party to the PCT after issuance of this sheet: |
| <input checked="" type="checkbox"/> LC Saint Lucia | <input checked="" type="checkbox"/> CR Costa Rica |
| <input checked="" type="checkbox"/> LK Sri Lanka | <input checked="" type="checkbox"/> DM Dominica |

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.


Box No. VI PRIORITY CLAIM		<input type="checkbox"/> Further priority claims are indicated in the Supplemental Box.		
Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is:		
		national application: country	regional application: regional Office	international application: receiving Office
item (1) 19/01/1999	GB9901139.7	UNITED KINGDOM		
item (2) 07/05/1999	GB9910476.2	UNITED KINGDOM		
item (3)				

☒ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office) identified above as item(s): (1) & (2)

* Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(iii)). See Supplemental Box.

Box No. VII INTERNATIONAL SEARCHING AUTHORITY			
Choice of International Searching Authority (ISA) (if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):		Request to use results of earlier search; reference to that search (if an earlier search has been carried out by or requested from the International Searching Authority):	
ISA /		Date (day/month/year)	Number Country (or regional Office)

Box No. VIII CHECK LIST: LANGUAGE OF FILING	
This international application contains the following number of sheets:	This international application is accompanied by the item(s) marked below:
request : 4	1. <input checked="" type="checkbox"/> fee calculation sheet
description (excluding sequence listing part) : 15	2. <input type="checkbox"/> separate signed power of attorney
claims : 2	3. <input type="checkbox"/> copy of general power of attorney; reference number, if any:
abstract : 1	4. <input type="checkbox"/> statement explaining lack of signature
drawings : -	5. <input type="checkbox"/> priority document(s) identified in Box No. VI as item(s):
sequence listing part of description : -	6. <input type="checkbox"/> translation of international application into (language):
Total number of sheets : 22	7. <input type="checkbox"/> separate indications concerning deposited microorganism or other biological material
	8. <input type="checkbox"/> nucleotide and/or amino acid sequence listing in computer readable form
	9. <input type="checkbox"/> other (specify):
Figure of the drawings which should accompany the abstract:	Language of filing of the international application:

Box No. IX SIGNATURE OF APPLICANT OR AGENT	
Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).	
 MARTIN G. HORNER.	

For receiving Office use only	
1. Date of actual receipt of the purported international application:	2. Drawings: <input type="checkbox"/> received: <input type="checkbox"/> not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:	
4. Date of timely receipt of the required corrections under PCT Article 1(2):	
5. International Searching Authority (if two or more are competent): ISA /	6. <input type="checkbox"/> Transmittal of search copy delayed until search fee is paid.

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Date of receipt of the record copy by the International Bureau:	